An adult male is eligible for participation in an NIH-funded clinical trial requiring documented informed consent using a combined consent/HIPAA research authorization form. The clinical research coordinator (CRC) was called to present the study in the outpatient clinic. After speaking with the CRC about the study, the eligible individual agreed to participate.

Questions:

1. Who should sign in the subject’s signature block?

2. Who should sign in the legally authorized representative lines?

3. Who should sign in the witness lines?

4. Who should sign in the PI/designee block?

5. Is additional documentation required? If yes, please specify.
SCENARIO 2

An adult female is eligible for participation in an NIH-funded clinical trial requiring documented informed consent using a combined informed consent/HIPAA research authorization form. The study was approved for adults with decisional impairment due to the nature of the study population.

The potential participant experienced head trauma and was unable to provide informed consent. A clinical research coordinator (CRC) was called to the ICU where the spouse was present. The CRC presented the study to the spouse, who agreed to study participation on behalf of the eligible patient the following day.

Questions:

1. Who should sign in the subject’s signature block?

2. Who should sign in the legally authorized representative lines?

3. Who should sign in the witness lines?

4. Who should sign in the PI/designee block?

5. Is additional documentation required? If yes, please specify.
SCENARIO 3

An adult male is eligible for participation in an NIH-funded clinical trial requiring documented informed consent using a combined consent/HIPAA research authorization form. The clinical research coordinator (CRC) was called to present the study in the outpatient clinic and learned that the individual is unable to read or write.

Questions:

1. What action steps do you recommend that the CRC take next?

2. Who should sign in the subject’s signature block?

3. Who should sign in the legally authorized representative lines?

4. Who should sign in the witness lines?

5. Who should sign in the PI/designee block?

6. Is additional documentation required? If yes, please specify.
SCENARIO 4

An adult female is eligible for participation in a privately funded clinical trial requiring documented informed consent using a combined informed consent/HIPAA research authorization form. After arriving in the ICU to speak with the potential participant, the clinical research coordinator (CRC) discovered that the ventilator and monitoring rendered the individual incapable of speech or moving her extremities, but cognitively able to provide informed consent.

Questions:

1. What action steps do you recommend that the CRC take next?

2. Who should sign in the subject’s signature block?

3. Who should sign in the legally authorized representative lines?

4. Who should sign in the witness lines?

5. Who should sign in the PI/designee block?

6. Is additional documentation required? If yes, please specify.
SCENARIO 5

An adult is potentially eligible for participation in an unfunded observational study requiring written informed consent. Final study eligibility is based on a fasting glucose level performed via finger stick at the enrollment visit, which requires that informed consent be obtained prior to fasting, and the individual lives two hours away.

Questions:

1. What alternatives would you recommend for obtaining informed consent without requiring four hours of travel time from the potential participant?

2. Who should sign in the subject’s signature block?

3. Who should sign in the legally authorized representative lines?

4. Who should sign in the witness lines?

5. Who should sign in the PI/designee block?

6. Is additional documentation required? If yes, please specify.